NEKTAR™

201 INDUSTRIAL ROAD
SAN CARLOS, CA 94070-6256
(MAIN) 650-631-3100 • (FAX) 650-620-6395

FACSIMILE TRANSMITTAL SHEET

August 11, 2008

TO: **MAIL STOP APPEAL BRIEF-PATENTS**
Commissioner for Patents
USPTO

FAX NO.: 571.273.8300

FROM: Naishadh N. Desai
(Reg. No. 50,630)

TELE. NO.: 650.631.3286

FAX NO.: 650.620.6395

RE: **U.S. Serial No: 10/714,575**

Attorney Docket No.: 0180.00

TOTAL NO. OF PAGES INCLUDING COVER: **28**

DOCUMENTS SUBMITTED:

- Transmittal Form (1 page)
- Fee Transmittal (1 page in DUPLICATE)
- Appeal Brief (24 pages)

Certificate of Facsimile Transmission:

I hereby certify that this correspondence is being facsimile transmitted to **MAIL STOP APPEAL BRIEF-PATENTS**, USPTO, at **(571) 273-8300**, on

DATE: AUGUST 11, 2008 BY: TINA M. INGRANDE

Signed Tina M. Ingrande

AUG 1 1 2008

PTO/SB/21 (08-08)
Approved for use through 08/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/714,575
Filing Date	November 14, 2003
First Named Inventor	Stelios TZANNIS
Art Unit	1644
Examiner Name	Yunsoo KIM
Attorney Docket Number	0180.00

ENCLOSURES *(Check all that apply)*

- [X] Fee Transmittal Form
- [ ] Fee Attached
- [ ] Amendment/Reply
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
- [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [X] Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) (please identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Nektar Therapeutics		
Signature			
Printed name	Naishadh N. Desai		
Date	August 11, 2008	Reg. No.	50,630

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Tina M. Ingrande		
Typed or printed name	Tina M. Ingrande	Date	August 11, 2008

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/17 (10-07)
Approved for use through 06/30/2010. OMB 0851-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2008

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 510.00

Complete if Known	
Application Number	10/714,575
Filing Date	November 14, 2003
First Named Inventor	Stelios TZANNIS
Examiner Name	Yunsoo KIM
Art Unit	1644
Attorney Docket No.	0180.00

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 50-0348 Deposit Account Name: Nektar Therapeutics

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	310	155	510	255	210	105	
Design	210	105	100	50	130	65	
Plant	210	105	310	155	160	80	
Reissue	310	155	510	255	620	310	
Provisional	210	105	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	210	105
Multiple dependent claims	370	185

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 20 or HP =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 3 or HP =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $260 ($130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____	/ 50 = _____ (round up to a whole number)	x 260.00	= 0.00

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Appeal Brief Fees (37 CFR 41.20(b)(2))	510.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 50,630	Telephone 650-631-3100
Name (Print/Type)	Naishadh N. Desai		Date August 11, 2008

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/17 (12-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2008

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 510.00

Complete if Known	
Application Number	10/714,575
Filing Date	November 14, 2003
First Named Inventor	Stelios TZANNIS
Examiner Name	Yunsoo KIM
Art Unit	1644
Attorney Docket No.	0180.00

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 50-0348 Deposit Account Name: Nektar Therapeutics

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	310	155	510	255	210	105	
Design	210	105	100	50	130	65	
Plant	210	105	310	155	160	80	
Reissue	310	155	510	255	620	310	
Provisional	210	105	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	210	105
Multiple dependent claims	370	185

Total Claims _____ - 20 or HP = _____ x Extra Claims _____ Fee ($) _____ = Fee Paid ($) _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims _____ - 3 or HP = _____ x Extra Claims _____ Fee ($) _____ = Fee Paid ($) _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims: Fee ($) _____ Fee Paid ($) _____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $260 ($130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets _____ - 100 = Extra Sheets _____ / 50 = Number of each additional 50 or fraction thereof _____ (round up to a whole number) x Fee ($) 260.00 = Fee Paid ($) 0.00

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Appeal Brief Fees (37 CFR 41.20(b)(2))	510.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 50,630	Telephone 650-631-3100
Name (Print/Type)	Naishadh N. Desai		Date August 11, 2008

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PATENT
Attorney Docket No. 0180.00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Stelios TZANNIS et al.		Examiner:	Yunsoo KIM
Serial No.:	10/714,575	Art Unit:	1644
Filed:	November 14, 2003	Conf. No.	1780
Title:	**ANTIBODY-CONTAINING PARTICLES AND COMPOSITIONS**		

APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The Appellants submit this Appeal Brief to the Board of Patent Appeals and Interferences on appeal from the decision of the Examiner of Group Art Unit 1644, dated 11 March 2008, and the Advisory Action dated 22 May 2008, finally rejecting claims 31-59. The final rejection of claims 31-59 is appealed. This Appeal Brief is filed by the statutory period ending on 11 August 2008, as set by the filing of a Notice of Appeal on 11 June 2008. The Commissioner is hereby authorized to charge Appellant's Deposit Account No. 50-0348 the fee of $510.00 for the filing of this Appeal Brief, and for any other fees required to make this Appeal Brief timely and acceptable to the Office.

TABLE OF CONTENTS

1.	Identification Page	1
2.	Table of Contents	2
3.	Real Party in Interest	3
4.	Related Appeals and Interferences	4
5.	Status of Claims	5
6.	Status of Amendments	6
7.	Summary of Claimed Subject Matter	7
8.	Grounds of Rejection to be Reviewed on Appeal	8
9.	Arguments	9
10.	Conclusion	14
11.	Claims Appendix	15
12.	Evidence Appendix	23
13.	Related Proceedings Appendix	24

REAL PARTY IN INTEREST

The real party in interest is Nektar Therapeutics, located at 201 Industrial Road, San Carlos, California 94070.

RELATED APPEALS AND INTERFERENCES

Appellants know of no other appeal or interference that will directly affect, or be directly affected by, or that will have a bearing on the Board's decision in the pending appeal.

RECEIVED
CENTRAL FAX CENTER
AUG 1 1 2008

STATUS OF CLAIMS

Claims 31-59 are pending in the application. Claims 1-74 were originally presented in the application. Claims 31-59 were elected in a response filed on 20 January 2006, pursuant to a Restriction Requirement Action issued by the Examiner on 10 January 2006. Upon issuance of next Office Action Examiner withdrew, without prejudice, claims 1-30 and 61-74 from consideration. Claims 57 and 58 have been cancelled without prejudice. Claims 31-56 and 59 stand finally rejected as discussed below. The final rejections of claims 31-56 and 59 are appealed. The pending claims are shown in the attached Claims Appendix.

STATUS OF AMENDMENTS

All claim amendments have been entered by the Examiner. Claims 57 and 58 were canceled in a response to the Final rejection by the Office. In the Advisory Action, issued on 29 April 2008, the Examiner indicated that for purpose of appeal, the amendments to these claims have been entered, and an explanation was provided indicating that the amendments do not place the application in condition for allowance. However, an ambiguity exists as the Advisory Action still refers to claims 31-59 as pending for the purpose of filing a Notice of Appeal and an Appeal Brief.

SUMMARY OF CLAIMED SUBJECT MATTER

Claimed embodiments of the invention provide reconstituted compositions comprising an antibody in an amount of from about 25 mg/mL to about 200 mg/mL, a diluent and an optional pharmaceutically acceptable excipient.

In the embodiment of independent claim 31, a reconstituted composition is claimed, comprising an antibody in an amount of from about 25 mg/mL to about 200 mg/mL (the Specification at page 21, paragraph [0098]), a diluent (the Specification at page 21, paragraph [0099])and an optional pharmaceutically acceptable excipient (the Specification at page 23, paragraph [0107]), wherein the reconstituted composition is (i) formed from adding the diluent to a spray-dried powder comprised of the antibody and the optional excipient, and (ii) is a visually clear reconstituted composition within about 10 minutes of being formed (the Specification at page 38, Table II).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Office Action has rejected claims 31-56, and 59 under 35 U.S.C. 112, first paragraph, as allegedly introducing New Matter.

The Office Action has rejected claims 31-56, and 59 under 35 U.S.C. 102(b) as allegedly being anticipated by Andya et al. (U.S. Patent No. 6,267,958).

ARGUMENTS

Rejection of claims 31-56, and 59 under 35 U.S.C. 112, first paragraph, as allegedly introducing New Matter.

The Examiner's Argument

The Examiner asserts that claims 31-59 contain subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. The Examiner asserts that the Specification as file[d] does not provide a written description for the phrase "about 25 mg/ml to about 200 mg/ml". The Specification on p. 22 lines 1-2 discloses the concentration ranges of "about 25 mg/ml to about 250 mg/ml".

The Appellants' Response to the Examiner's Argument

The Office Action has rejected claims 31-59 under 35 U.S.C. 112, first paragraph, as allegedly introducing New Matter. The Office Action alleges that [T]he specification as filed does not provide such written description of the phrase "about 25 mg/ml to **about 200 mg/ml**" other than range of "about 25 mg/ml to **about 250 mg/ml**" on p. 22 lines 1-2 of the specification. (Emphases in the Office Action) Appellants respectfully traverse the rejection and provide following remarks.

Appellants reproduce the relevant sections from the Specification for the discussion (Paragraphs [0100-0102], Specification at pages 21-22).

> **[0100]** The amount of the diluent added to the powder is an amount such that the resulting concentration is suited to the intended application. Those of ordinary skill in the art know or can experimentally determine an appropriate antibody concentration for any given application. Typically, however, the concentration of the antibody in the reconstituted composition is about 1000 mg/mL or less. Thus, for example, completely spray drying a feed liquid comprising 1000 mg of an antibody and completely recovering the entire spray-dried powder will require 1 mL of diluent to form a reconstituted composition having an antibody concentration of 1000 mg/mL, 2 mL of diluent to form a reconstituted composition

having an antibody concentration of 500 mg/mL, and so forth.

[0101] For subcutaneous administration, a preferred concentration range of the antibody in the reconstituted composition is from about 25 mg/mL to about 750 mg/mL, more preferably from about 25 mg/mL to about 500 mg/mL, still more preferably from about 50 mg/mL to about 450 mg/mL, yet still more preferably from about 70 mg/mL to about 400 mg/mL, and still more preferably from about 100 mg/mL to about 300 mg/mL. Another preferred range of the antibody is from about 25 mg/mL to about 250 mg/mL.

[0102] With respect to intravenous administration, exemplary antibody concentrations include from about 2.5 mg/mL to about 100 mg/mL, from about 5 mg/mL to about 75 mg/mL, and from about 10 mg/mL to about 50 mg/mL.

The Specification teaches that the spray dried antibody powders may be reconstituted anywhere from about 2.5 mg/mL to about 1000 mg/mL. Further, the specification teaches that depending on the route of administration (among other things); one skilled in the art may choose varying reconstituted concentrations. Furthermore, the Specification specifically mentions the following concentrations: 2.5 mg/mL, 5 mg/mL, 7.5 mg/mL, 10 mg/mL, 25 mg/mL, 25 mg/mL, 50 mg/mL, 70 mg/mL, 75 mg/mL, 100 mg/mL, 250 mg/mL, 300 mg/mL, 400 mg/mL, 450 mg/mL, 500 mg/mL, 750 mg/mL, and 1000 mg/mL. Further, a careful reading of Example 1 at page 37, paragraph [0160] reveals that spray dried formulations reconstituted at 50, 100, and 200 mg/mL maintained protein integrity and were stable.

Thus, Appellants here are describing series of ranges for various preferred embodiments, which set boundaries for what is within the range for a specific preferred embodiment. A range encompasses all variables that are within that range. A range is not its edges only. Appellants submit that all of the concentrations between about 2.5 mg/mL to about 1000 mg/mL are encompassed and enabled, and that Appellants could choose any concentration between these limitations to write their claims.

To the extent that the exact phrase "about 25 mg/mL to about 200 mg/ mL" together in claim 31 represents the introduction of "new matter," Appellants respectfully submit that such a position is contrary to well-established case law in that a disclosure including multiple ranges provides adequate support for reciting portions of those ranges. *See In re Wertheim*, 191 USPQ 90 (CCPA 1976) (range of 25 to 60% with examples at 36% and 50% found to be adequate description for a range of 35 to 60%); In re Voss, 194 USPQ 267 (CCPA 1977) (range of 20 to 100% provided description for range of 50 to 100%); In re Blaser, 194 USPQ 122 (CCPA 1977) (range of 60 to 200°C provided adequate description for 80 to 200°C); In re Waymouth, 179 USPQ 627 (CCPA 1973) (range of 450 to 700°C was claiming same range as claim specifying a minimum temperature of 580°C); McLaughlin v. Roberts, 197 USPQ 831 (Bd. Pat. App. & Int. 1978) (range of 10 to 79% with preferred ranges of 40 to 79% and 40 to 60% provided adequate support to claim range of 10 to 25%). Therefore, Appellants submit that it is improper for the Office to conclude that "about 200 mg/mL" is not supported by the Specification.

Appellants submit that in view of the foregoing the amendments to claim 31 are appropriate, and respectfully submit that rejection based on 35 USC 112, first paragraph should be withdrawn.

Rejection of claims 31-56, and 59 under 35 U.S.C. 102(b) as allegedly being anticipated by Andya et al. (U.S. Patent No. 6,267,958).

The Examiner's Argument

The Examiner asserts that '958 patent teaches a stable reconstituted formulation comprising an antibody of about 100 mg/ml, diluent, buffer, sucrose as excipient (claims

1-8, col. 17, lines 1-40, Tables 5-6, in particular). The Examiner further asserts that '958 teaches the antibody being full length, fragments, grafted, humanized, IgG or IgE, and that expedient being buffer, diluent being water, etc., to reject the dependent claims.

The References

US Patent No. 6,267,958 to Andya et al. teach a stable isotonic reconstituted formulation comprising an antibody in an amount of about 50 mg/mL to about 400 mg/mL and a diluent, which reconstituted formulation has been prepared from a lyophilized mixture of the antibody and a lyoprotectant which prevents or reduces chemical or physical instability of the antibody upon lyophilization and subsequent storage, wherein the molar ratio of lyoprotectant:antibody is about 100-510 mole lyoprotectant:1 mole of antibody, and wherein the antibody concentration in the reconstituted formulation is about 2-40 times greater than the antibody concentration in the mixture before lyophilization.

The Appellants' Response to the Examiner's Argument

The rejection is respectfully traversed in view of the following remarks.

The standard for anticipation is rigorous requiring that every element of the claimed invention be disclosed by a single prior art reference. *See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed.Cir.1992); *Scripps*, 927 F.2d at 1576-77; *Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed.Cir.1984).

The Office Action states that the "patentability of the product does not depend on its method of production." Citing Andya et al. at claims 1-8 and 47 and column 17, lines 1-40, and Table 5-6, in particular, the Examiner alleges that the claimed antibody formulation and the referenced antibody formulation both comprise an antibody; diluent, buffer and sucrose as an excipient. The Examiner concludes that "being visually clear upon reconstitution within about 10min" is inherent property of the antibody composition comprising antibody, histidine and polysorbate."

In response, Appellants point out that the claims do not simply recite a reconstituted composition being "visually clear upon reconstitution." Instead, the claims recite (among other things) that the reconstituted composition "is a visually clear reconstituted composition within about 10 minutes of being formed." Emphasis added. In view of the different reconstitution times associated with the lyophilized formulations shown in the specification at paragraph **[0162]** (which are also of the type disclosed in Andya et al.) and the spray dried formulations encompassed by the claims, it simply cannot be said that a visually clear reconstituted composition within about 10 minutes of being formed is "an inherent property of antibody formulations" generally.

Again, Appellants emphasize that their claims require a reconstituted composition having the feature of visual clarity within about 10 minutes of being formed. Appellants have specifically demonstrated that reconstituted lyophilized compositions -- such as the type disclosed in Andya et al. -- will not inherently become a visually clear reconstituted composition within about 10 minutes of being formed. Further, a close reading of Andya et al. only reveals that the "time required for reconstitution will depend, e.g., on the type of diluent, amount of excipient(s) and protein." See Andya et al. at Column 17, lines 23-25. In addition, Andya et al. fails to disclose the feature of a spray-dried powder, a feature recited in the only pending independent claim. Consequently, as the cited art fails to teach each and every feature recited in the claims, Appellants respectfully request that the rejection of claims 31-59 under 35 U.S.C. 102(b) should be removed. Reconsideration and removal of the rejection are respectfully requested.

RECEIVED
CENTRAL FAX CENTER
AUG 1 1 2008

CONCLUSION

For the reasons advanced above, the Appellants respectfully urge that the rejections of claims 31-56 and 59 as are improper. Reversal of the rejections in this appeal is respectfully requested by the Appellants.

Respectfully submitted,
Nektar Therapeutics

Date: 11 AUGUST 2008 By: _____

Nalshadh N. Desai, Ph.D.
Registration No. 50,630

CORRESPONDENCE ADDRESS:
Customer No. 21968
Nektar Therapeutics
201 Industrial Road
San Carlos, CA 94070
(650) 631-3100 (Telephone)
(650) 620-6395 (Facsimile)

CLAIMS APPENDIX

1. (Withdrawn) A composition comprising antibody-containing particles, wherein the particles have a mass median diameter of greater than 7.5 μm and less than 100 μm.

2. (Withdrawn) The composition of claim 1, wherein the particles have a mass median diameter of greater than 10 μm and less than 100 μm.

3. (Withdrawn) The composition of claim 1, wherein the antibody is an antibody fragment.

4. (Withdrawn) The composition of claim 3, wherein the antibody fragment is selected from the group consisting of Fab, $F(ab)_2$, Fv, and single polypeptide chain binding molecule.

5. (Withdrawn) The composition of claim 1, wherein the antibody is a full-length antibody.

6. (Withdrawn) The composition of claim 1, wherein the antibody is murine.

7. (Withdrawn) The composition of claim 1, wherein the antibody is chimeric.

8. (Withdrawn) The composition of claim 1, wherein the antibody is CDR-grafted.

9. (Withdrawn) The composition of claim 1, wherein the antibody is humanized.

10. (Withdrawn) The composition of claim 1, wherein the antibody is an antibody-conjugate.

11. (Withdrawn) The composition of claim 1, wherein the antibody or antibody fragment is a type selected from the group consisting of IgE, IgG, and IgM.

12. (Withdrawn) The composition of claim 11, wherein the antibody is an IgG-type.

13. (Withdrawn) The composition of claim 1, further comprising a pharmaceutically acceptable excipient.

14. (Withdrawn) The composition of claim 13, wherein the pharmaceutically acceptable excipient is present in the antibody-containing particles.

15. (Withdrawn) The composition of claim 13, wherein the pharmaceutically acceptable excipient is comprised of particles separate and distinct from the antibody-containing particles.

16. (Withdrawn) The composition of claim 13, wherein the excipient is selected from the group consisting of amino acid, amino acid derivative, oligopeptide, carbohydrate, inorganic salts, antimicrobial agents, antioxidants, surfactants, buffers, acids, bases, and combinations thereof.

17. (Withdrawn) The composition of claim 16, wherein the excipient is a carbohydrate.

18. (Withdrawn) The composition of claim 17, wherein the carbohydrate is selected from the group consisting of fructose, maltose, galactose, glucose, mannose, sorbose, lactose, sucrose, trehalose, cellobiose, raffinose, melezitose, maltodextrans, dextrans, starches, mannitol, xylitol, lactitol, glucitol, pyranosyl sorbitol, myoinositol, and combinations thereof.

19. (Withdrawn) The composition of claim 17, wherein the carbohydrate is selected from the group consisting of sucrose and trehalose.

20. (Withdrawn) The composition of claim 16, wherein the excipient is selected from a salt or buffer.

21. (Withdrawn) The composition of claim 20, wherein the salt or buffer is selected from the group consisting of citric acid, sodium phosphate monobasic, sodium phosphate dibasic, and combinations thereof.

22. (Withdrawn) The composition of claim 16, wherein the excipient is a surfactant.

23. (Withdrawn) The composition of claim 22, wherein the surfactant is selected from the group consisting of Tween-20, Tween-80, and combinations thereof.

24. (Withdrawn) The composition of claim 16, wherein the excipient is an amino acid.

25. (Withdrawn) The composition of claim 24, wherein the amino acid is selected from the group consisting of leucine, histidine, and combinations thereof.

26. (Withdrawn) The composition of claim 1, wherein the composition is housed in a syringe.

27. (Withdrawn) The composition of claim 1, wherein the composition is housed in a vial.

28. (Withdrawn) The composition of claim 1, wherein the antibody is noncrystalline.

29. (Withdrawn) The composition of claim 1, wherein the antibody is partially amorphous.

30. (Withdrawn) The composition of claim 1, having substantially no aggregates.

31. (Previously presented) A reconstituted composition comprising an antibody in an amount of from about 25 mg/mL to about 200 mg/mL, a diluent and an optional pharmaceutically acceptable excipient, wherein the reconstituted composition is (i) formed from adding the diluent to a spray-dried powder comprised of the antibody and the optional excipient, and (ii) is a visually clear reconstituted composition within about 10 minutes of being formed.

32. (Original) The composition of claim 31, in sterile form.

33. (Original) The composition of claim 31, wherein the antibody is an antibody fragment.

34. (Original) The composition of claim 33, wherein the antibody fragment is selected from the group consisting of Fab, $F(ab)_2$, Fv, and single polypeptide chain binding molecule.

35. (Original) The composition of claim 31, wherein the antibody is a full-length antibody.

36. (Previously presented) The composition of claim 31, wherein the antibody is murine.

37. (Previously presented) The composition of claim 31, wherein the antibody is chimeric.

38. (Previously presented) The composition of claim 31, wherein the antibody is CDR-grafted.

39. (Previously presented) The composition of claim 31, wherein the antibody is humanized.

40. (Previously presented) The composition of claim 31, wherein the antibody is an antibody-conjugate.

41. (Previously presented) The composition of claim 31, wherein the antibody or antibody fragment is a type selected from the group consisting of IgE, IgG, and IgM.

42. (Original) The composition of claim 41, wherein the antibody is an IgG-type.

43. (Original) The composition of claim 31, wherein the pharmaceutically acceptable excipient is present.

44. (Original) The composition of claim 43, wherein the excipient is selected from the group consisting of amino acid, amino acid derivative, oligopeptide, carbohydrate, inorganic salts, antimicrobial agents, antioxidants, surfactants, buffers, acids, bases, and combinations thereof.

45. (Original) The composition of claim 44, wherein the excipient is a carbohydrate.

46. (Original) The composition of claim 45, wherein the carbohydrate is selected from the group consisting of fructose, maltose, galactose, glucose, mannose, sorbose, lactose, sucrose, trehalose, cellobiose, raffinose, melezitose, maltodextrans, dextrans, starches, mannitol, xylitol, lactitol, glucitol, pyranosyl sorbitol, myoinositol, and combinations thereof.

47. (Original) The composition of claim 45, wherein the carbohydrate is selected from the group consisting of sucrose and trehalose.

48. (Original) The composition of claim 44, wherein the excipient is selected from a salt or buffer.

49. (Original) The composition of claim 48, wherein the salt or buffer is selected from the group consisting of citric acid, sodium phosphate monobasic, sodium phosphate dibasic, and combinations thereof.

50. (Original) The composition of claim 44, wherein the excipient is a surfactant.

51. (Previously presented) The composition of claim 50, wherein the surfactant is a polysorbate.

52. (Original) The composition of claim 44, wherein the excipient is an amino acid.

53. (Original) The composition of claim 52, wherein the amino acid is selected from the group consisting of leucine, histidine, and combinations thereof.

54. (Original) The composition of claim 31, wherein the composition is housed in a syringe.

55. (Original) The composition of claim 31, wherein the composition is housed in a vial.

56. (Original) The composition of claim 31, wherein the diluent is selected from the group consisting of bacteriostatic water for injection, dextrose 5% in water, phosphate-buffered saline, Ringer's solution, saline, sterile water, deionized water, and combinations thereof.

57-58. (Canceled)

59. (Original) The composition of claim 31, having substantially no aggregates.

60. (Withdrawn) A method for preparing a reconstituted composition comprising the steps of providing a spray-dried powder comprised of an antibody and adding a diluent in order to form the reconstituted composition, wherein the antibody is present in the reconstituted composition in an amount of from about 25 mg/mL to about 1000 mg/mL.

61. (Withdrawn) The method of claim 60, wherein the reconstituted composition comprises an excipient.

62. (Withdrawn) The method of claim 61, wherein the excipient is present in the spray-dried powder.

63. (Withdrawn) The method of claim 61, wherein the excipient is added with or after the step of adding the diluent.

64. (Withdrawn) The method of claim 60, wherein the step of providing the spray-dried powder is comprised of combining the antibody in a liquid to form a liquid feed and spray drying the liquid feed to form the spray-dried powder.

65. (Withdrawn) The method of claim 60, wherein the reconstituted composition has substantially no aggregates.

66. (Withdrawn) The method of claim 60, wherein the reconstituted composition becomes visually clear within about 15 minutes of adding the diluent.

67. (Withdrawn) The method of claim 66, wherein the reconstituted composition becomes visually clear within about 10 minutes of adding the diluent.

68. (Withdrawn) The method of claim 67, wherein the reconstituted composition becomes visually clear within about 5 minutes of adding the diluent.

69. (Withdrawn) The method of claim 60, wherein the diluent is selected from the group consisting of diluent is selected from the group consisting of bacteriostatic water for injection, dextrose 5% in water, phosphate-buffered saline, Ringer's solution, saline, sterile water, deionized water, and combinations thereof.

70. (Withdrawn) The method of claim 60, wherein the antibody is present in the reconstituted composition in an amount of from about 25 mg/mL to about 250 mg/mL.

71. (Withdrawn) A method of administering a composition to a patient comprising administering, via injection, a therapeutically effective amount of an antibody present in a reconstituted composition, wherein the reconstituted composition is comprised of an antibody concentration of from about 25 mg/mL to about 1000 mg/mL, a diluent and an optional excipient, wherein the reconstituted composition is formed from a spray-dried powder comprised of the antibody and the optional excipient.

72. (Withdrawn) The method of claim 71, wherein the injection is a subcutaneous injection.

73. (Withdrawn) The method of claim 71, wherein the injection is an intramuscular injection.

74. (Withdrawn) The method of claim 71, wherein the injection is an intravenous injection.

EVIDENCE APPENDIX

The Appellants state that there is no evidence submitted under 37 C.F.R. §1.130, 1.131, or 1.132, or other evidence entered by the Examiner or relied upon by the Appellants in the Appeal.

RELATED PROCEEDINGS APPENDIX

The Decision of the Board of Patent Appeals and Interference in Patent Interference No. 105,219, rendered on 26 December 2007 is attached herewith.